Life Spine®

K073274

510(k) Summary

MAR 17 2008

510(k) Summary – Spinal Sphere System

Preparation Date:	November 20, 2007
Submitted By:	Life Spine 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
Contact:	Rebecca M. Brooks Life Spine 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
Proprietary Trade Name:	Spinal Sphere System
Classification Name:	Intervertebral Fusion Device With Bone Graft, Solid-Sphere, Lumbar
Product Code:	NVR
Predicate Device:	Satellite™ Spinal System (Medtronic Sofamor Danek, K051320 and K060415)

Device Description:
The Spinal Sphere System consists of spheres manufactured from either CoCrMo or PEEK-OPTIMA. The device may be implanted from L3 to S1 to provide temporary stabilization in order to help promote fusion. The spheres are available in a variety of sizes.

Intended Use of the Device:
The Spinal Sphere System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. Properly used, this internal fixation device is intended and designed solely for holding bone parts in alignment while they heal. The Spinal Sphere System is intended to be used with bone graft. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. It is not intended for use in motion-sparing, non-fusion procedures.

Substantial Equivalence:
The Spinal Sphere System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Life Spine
% Rebecca M. Brooks
Project Coordinator
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169

MAR 17 2008

Re: K073274
Trade/Device Name: Spinal Sphere System
Regulation Number: Pre-amendment
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: NVR
Dated: February 28, 2008
Received: February 29, 2008

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print:

> The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

Indications for Use

510(k) Number (if known): K073274

Device Name: Spinal Sphere System

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Prescription Use __x__ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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